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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/781,721	02/12/2001	William Richard Dubrul	ARTM 1008-5 US	8945
34263	7590	02/19/2004		
O'MELVENY & MEYERS 114 PACIFICA, SUITE 100 IRVINE, CA 92618				
			EXAMINER WILLIAMS, CATHERINE SERKE	
			ART UNIT	PAPER NUMBER
			3763	29
DATE MAILED: 02/19/2004				

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

Application No.

09/781,721

Applicant(s)

DUBRUL ET AL.

Examiner

Catherine S. Williams

Art Unit

3763

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 08 December 2003.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 26-30, 32 and 34-55 is/are pending in the application.
- 4a) Of the above claim(s) 39-55 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 26-30, 32 and 34-38 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |   |   |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)  | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date <u>23</u> . | 6) <input type="checkbox"/> Other: _____  |

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## DETAILED ACTION

### *Claim Rejections - 35 USC § 102*

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 26-27, 29 and 32 are rejected under 35 U.S.C. 102(e) as being anticipated by Klein (US Pat# 5,810,767). Klein discloses a method and apparatus for intraluminal drug delivery that includes positioning a porous tubular braid with a contact dispensable agent at a target site within a passageway of a body; expanding the braid against the body tissue, and dispensing the agent from the braid into the body tissue. See 6:19-39. The braid is expanded by a radially-expandable element (13). While the reference does not specifically disclose contracting and removing the radially-expansible element and the tubular braid from the body, it is considered inherent since the element and the braid are structurally attached and the device is designed to be removed from the body. The device further includes a balloon (B see figure 12). The dispensing step is carried out as a result of the expanding step. See 11:31-12:25. The porous tubular braid is not bioabsorbable and may be constructed from nylon. See 7:50.

Claims 26 and 28-30 are rejected under 35 U.S.C. 102(e) as being anticipated by Brown, III et al (US Pat# 6,219,577). Brown discloses a iontophoresis catheter for local drug delivery that includes positioning a porous tubular braid with a contact dispensable agent (see 9:17-22) at

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a target site within a passageway of a body; expanding the braid against the body tissue, and dispensing the agent from the braid into the body tissue. See 10:35-59. The braid is expanded by a radially-expandable element (24) within the braid. While the reference does not specifically disclose contracting and removing the radially-expansible element and the tubular braid from the body, it is considered inherent since the element and the braid are structurally attached and the device is designed to be removed from the body. The braid include absorbent polyester monofilaments. See 9:4-9. The dispensing step is carried out as a result of the expanding step using iontophoresis. See 9:4-30.

Claims 34-35 and 37-38 are rejected under 35 U.S.C. 102(e) as being anticipated by Shaknovich (US Pat# 5,749,890). Shaknovich discloses a method and system for stent placement that includes positioning an inflatable balloon at a target site, inflating the balloon, deflating the balloon, moving the balloon distally, positioning a stent releasably mounted on a second position on the catheter at the target site, and expanding the stent. See figures 6-15 and 9:27-55. While the reference does not specifically disclose removing the catheter and balloon from the body, it is considered inherent since catheter and balloon are not for permanent placement in the body and the stent is eventually released from the catheter shaft after the expanding step. See figure 15. The stent may be self-expanding or not self-expanding. See 10:65+. An agent may be dispensed into the target site. See 11:24-29.

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claim 36 is rejected under 35 U.S.C. 103(a) as being unpatentable over Shaknovich.

Shaknovich meets the claim limitations as described above but fails to include axially compressing the stent while expanding.

However, Shaknovich does disclose the use of self-expanding stent with the catheter system. It is well known in the art that many self-expanding stents "self-expand" by being constructed to compress in the axial direction in order to expand in the radial direction.

At the time of the invention, it would have been obvious to use a self-expanding stent that includes axial compression to generate radial expansion. Shaknovich discloses the use of self-expanding stent, therefore a combination is proper. Additionally, the motivation for incorporating a stent as described above would have been to use a well known type of self-expanding stent in order to maintain or enhance the overall reliability of the device.

***Response to Arguments***

Applicant's arguments with respect to claims 26-30, 32, 34-38 have been considered but are moot in view of the new ground(s) of rejection.

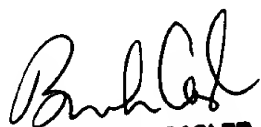
***Conclusion***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Catherine S. Williams whose telephone number is 703-308-4846. The examiner can normally be reached on Monday - Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brian Casler can be reached on 703-308-3552. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Catherine S. Williams *ds*  
February 9, 2004

  
**BRIAN L. CASLER**  
**SUPERVISORY PATENT EXAMINER**  
**TECHNOLOGY CENTER 3700**